REMARKS

Applicant appreciatively thanks the Examiner for allowing Claims 58-76 and looks forward to their issuance. Additionally, Applicant respectfully requests reconsideration of the non-allowed claims in view of the above Amendment and the following remarks.

Pending in this Application are Claims 1-99. **Claims 58-76 have been allowed,** Claims 11-14, 16, 17, 19, 20, 30-33, 35, 36, 38, 39, 46, 48-51, 53, 54, 56, 57, 83-86 and 94-97 are objected to; and Claims 1-10, 15, 18, 21-29, 34, 37, 40-45, 47, 52, 55, 77-82, 87-93, 98 and 99 have been rejected.

Claims 1, 5, 6, 9, 23, 24, 25, 28, 43, 44, 46, 77, 86, 89, 97, and 99 have been amended;

Claims 10, 21, 29, 78, 81-85, 87, 90-96, and 98 have been canceled; and

Claims 2-4, 7, 8, 10-20, 22, 26, 27, 30-42, 45, 44-76, 79, 80, and 88 are original.

Amendments to Claims:

The Amended claims find support throughout the original specification or original claims, including the following sections:

Claims 1, 23, and 44:	Support for the amendments that include a synthetic muscle specific promoter for independent Claims 1, 23, and 44 find support in the specification at paragraphs: [0077]; [0085]; [0106]; [0126-0131]; Table 2; and [0162-0167]. Additionally, these claims also contain the limitations of some canceled dependant claims, as discussed in more detail below.
Claim 77	This amendment combines some of the limitations of canceled Claims 82 and 85 into the amended claim.
Claim 89	This amendment combines some of the limitations of canceled Claims 91 and 96 into the amended claim.
Claims 2, 5, 6, 9, 24, 25, 28, 43, 46, 86, 97, and 99	These claims have been amended in order to maintain proper antecedent basis of terms, or to maintain proper dependency from the corresponding amended independent or canceled claims.

I. Claim Objections

The Examiner has objected to Claim 93 because it was a duplicate of Claim 92. In response Applicant has canceled Claim 93.

II. Claim Rejection –35 U.S.C. §112 Second Paragraph

The Examiner is of the opinion that Claims 5 and 25 lacks prior antecedent basis of the term *"the electroporation method"* since it is recited in the alternative in the claim from which it depends.

In response, Applicant has amended Claim 5 and Claim 25 to remove the term *"the electroporation method."*

II. Claim Rejection –35 U.S.C. §102(e)

The Examiner has rejected Claims 1, 10, 15, 18, 21-24, 77, 78, 81, 82, 87-93, 98 and 99 for being anticipated by U.S. Patent 6,423,693, issued to Schwartz ("the '693 Patent). More specifically, the Examiner is of the opinion that the '693 Patent discloses the identification and use of nucleic acid sequences that confer advantageous tissue targeting, expression, and secretion properties for encoding GHRH, and describes how GHRH enhances the immune system in animals, and is used to treat chronic diseases, which thereby is considered to decrease cull and improve body condition.

Applicant respectfully submits that the '693 Patent DOES NOT describe or discloses methods that are related the current claims, as amended, such as introducing an isolated nucleic acid expression construct to increase a body condition score, or reduce culling, mortality and morbidity in farm animals.

More specifically, the plasmids disclosed in the '693 Patent contain natural sequences for promoter and transgenes (*e.g* the skeletal alpha actin promoter and not a synthetic muscle specific promoter). Applicant has amended independent Claims 1, 23, and 44 to include the limitation of a "synthetic muscle specific promoter" in the isolated nucleic acid expression construct. This limitation is not present in the '693 Patent. Applicant respectfully submits that the dependant claims of the amended Claims 1, 23, and 44 (e.g. 10, 15, 18, 21, 22, and 24), also contain the limitation of a synthetic muscle specific promoter limitation, which was not present in the '693 Patent.

Additionally, Applicant respectfully submits that the '693 Patent DOES NOT discloses inventions that are related to using growth hormone secretagogue molecules that comprise an isolated biologically active polypeptide generated from a recombinant nucleic acid expression construct that encodes a GHRH molecule for improving body condition scores, and reducing culling, mortality and morbidity in farm animals, as indicated in Claims 77 and 89, as amended.

Support for the amended Claims 77 and 89 can be found in the specification in paragraphs [0005]; [0006]; 00014]; [0099]; [0103]; [0117]; [0127]; as well as from the canceled Claims 82, 85, 91, and 96.

The court has held that: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegraal Bros. v Union Oil Co. of California*, 2 U.S.P.Q. 2d 1051, 1053 (Fed Cir 1982)).

Thus, the '693 Patent cannot anticipate Claims 1, 10, 15, 18, 21-24, 77, 78, 81, 82, 87-93, 98 and 99 of the current application under 35 U.S.C. §102(e), because the '693 patent does not describe methods for increasing body condition scores and/or reducing culling, mortality and morbidity in farm animals using nucleic expression vectors with synthetic muscle promoters or secretagogue molecules, as indicated in the current claims, as amended.

For these reasons, Applicant respectfully submits that Claims 1, 10, 15, 18, 21-24, 77, 78, 81, 87-90, 92, 93, 98 and 99 are patentable over the '693 Patent.

Additionally, Applicant respectfully submits that an affidavit 37 C.F.R. 1.132 is NOT needed at this time because the invention disclosed in the '693 Patent is different than the invention claimed in the current application.

II. Claim Rejection –35 U.S.C. §103(a)

(1) the '693 Patent. The Examiner has rejected Claims 2, 7-9, 26, 27, 28, 29, 34, 37, 40-45, 47, 52 and 55 as being unpatentable over the '693 Patent. More specifically, the Examiner is of the opinion that since the mortality rate is decrease by 5% (from 20% to 15% as recited in Claim 2, or that the milk production is increase from 8-18% as recited in Claim 45, it is not specifically claimed, but since the general conditions are disclosed, through routine experimentation it would have been obviously to one skilled in the art to discover this range.

Applicant submits that according to the Manual of Patent Examining Procedure -(MPEP) §2143 there are three requirements for Prima Facie Obviousness:

1) Some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

2) A reasonable expectation of success; and

3) Prior art reference (or references when combined) must each list or suggest all of the claim limitations.

Applicant respectfully submits that NONE of the above requirements of obviousness have been met for comparing the teachings of '693 Patent to the claims of the current application, as amended. More specifically, Applicant's response to the Examiner's claim rejection under 35 U.S.C. §102(e) indicate that several claim limitations (e.g. introducing a nucleic acid expression vector having an synthetic muscle promoter to reducing culling, mortality and morbidity in farm animals) of the current invention that are not present or suggested in the '693 Patent, see above for details.

Applicant respectfully submits that the '693 Patent described experiments performed in mice, a lower phylogeny species when compared to farm animals, which does not always translate into larger mammals, thus routine experimentation would not have been obvious to one skilled in the art. As a specific example, the '693 Patent discloses the use of 0.1-0.3 mg of plasmid in a 25 g mouse. Thus, if a similar protocol were to be utilized in a 500 kg dairy cow, the injection amount of plasmid would need to be approximately 4 kg, which was NOT indicated in Applicant's claimed invention. Because the claims are read in light of the specification, Applicant demonstrated that about 2.5 mg plasmid could be utilized in a cow of approximately 500 kg in order to achieve the desired results, which would indicate a 12.5 fold increase in dose for a 20,000 fold increase in weight. Applicant's dependant Claims 8, 27, 47, 61, 67, and 73 also indicate this distinction.

Additionally, numerous published studies in the specialty literature at the time of filling were indicating that for large animals and humans repeat administration of plasmid would be mandatory. The Applicant has indicated and shown that a single injection of the said plasmids is

sufficient for long term effects. One of ordinary skill in the art would not have had a reasonable expectation of successfully decreasing a single dose based upon the teaching of the '693 Patent and other literature at the time of the invention.

Applicant submits that the '693 Patent does NOT teach any methods to improve the body composition scores of the animals, NOR is there a teaching of the morbidity, mortality or culling, NOR is there a teaching of any other such parameter that are described and claimed in the current application, or the use of GHRH secretagogues to those ends. Thus, the '693 reference cannot represent a 35 U.S.C. §103(a) prior art reference to Applicant's invention.

Additionally, the Examiner has commented on the recited subject matter dependent upon the type of animal on which the procedure is performed. More specifically, the animal would have to be one whose cells are diploid in nature, and it would have been obvious to use an animal having such diploid cells.

In response, Applicant submits that Claim 9 and Claim 28 attempted to underline that the treated animals are NOT genetically modified organisms or transgenics, thus, they are not treated at the level of gametes, and the effect of the method of treatment was not genetically transmissible. Applicant has amended Claim 9 and Claim 28 to recite that the muscle cells treated in the farm animals were diploid.

(2) the '693 Patent in view of the US 2003/0074679 Application the '679 Reference. The Examiner is of the opinion that the '693 Patent and the '679 Reference disclose similar methods of administration of nucleic acid sequences to animals as disclosed in Claims 3-5, 79, and 80 of the current application. More specifically, the method of administration of nucleic acid sequences through a parenteral route to enhance growth of offspring is similar.

In response, the Applicant respectfully submits that the '693 Patent is not a 35 U.S.C. §103 reference for the reasons explained above.

Additionally, the '679 Reference teaches the effects of a plasmid-mediated GHRH supplementation on growth hormone, insulin-like growth factor I, growth rate, feed efficiency, and milk suckled on the **OFFSPRING** of the treated animals, and **NOT on the animals that**

were treated directly. See page 6, paragraph [0015]; page 10, paragraph [0020]; page 17, paragraph [0067]; page 22, paragraph [0081]; page 51, paragraph [0167]; page 52, paragraph [0170]; page 53, paragraph [0174]; page 58, paragraph [0185] and Table 15 on page 57 of the reference. The reference describes that the **OFFSPRING** of treated animals were studied in detail, including their morbidity and mortality, and **NOT** the treated animals themselves. Because the milk suckled by the **OFFSPRING** of the treated animals was not measured directly, the reference could not have indicated an increase of milk production in the sows directly.

Furthermore, as seen on page 39, paragraph [0138]; and page 40, paragraph [0139] of the '679 Reference, the increase growth of the offspring of the treated animals was proportional in all body components. Page 39, paragraph [0138] has this to say:

"Body composition studies by densitometry, K40 potassium chamber and neutron activation chamber showed a proportional increase of all body components in GHRH-injected animals, with no sign of organomegaly, relative proportion of fat and associated pathology."

Thus, this finding cannot enter in the definition of better "body condition scores," as these scores are based on a whole organism basis, and could not be used when considering a herd cull, as defined on page 19 paragraph, [0052] of Applicant's application.

The distinction between a mother treated with a nucleic acid composition and the offspring of the treated mother is considered not directly comparable by Applicant. For comparison purposes only, one can compare the detrimental effects on offspring from mothers who smoke during pregnancy. The smoking mother generally run the risk to giving birth to children with low birth weight (the so called "small to date" babies), while the mothers are not smaller themselves. Also, the offspring, but not the smoking mother, can have long-term adverse developmental effects from the mother's smoking during pregnancy, including significant higher risk of becoming a smoker, or having a decreased cognitive index.

Applicant submits that since the '679 Reference is related to the offspring of a treated animal and not the treated animal itself, thus, the '679 Reference cannot be a 35 U.S.C. §103 prior art reference to Applicant's current invention.

Conclusion

Applicant respectfully submits that, in light of the foregoing Amendment and remarks, the amended claims are in condition for allowance. A Notice of Allowance is therefore respectfully requested for Claims 1-9, 11-20, 22-28, 30-56, 58-76, 77, 79, 80, 86, 88, 89, 97 and 99.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

T. Ling Chwang

T. Ling Chwang
Registration No. 33,590
JACKSON WALKER L.L.P.
2435 North Central Expressway, #600
Richardson, TX 75080
Tel: (972) 744-2919
Fax: (972) 238-3319

May 20, 2005

Date